EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Health systems and products
e-Health and Health Technology Assessment

ANNEX 6

Brussels, 1st October 2013

1ST HTA NETWORK MEETING
16 OCTOBER 2013, BRUSSELS
COVER NOTE BY SECRETARIAT

Subject: Topic 1: Strategic discussion on European cooperation on HTA

Issue at stake / request to the HTA network
Before starting considering a multiannual work programme for the HTA network (topic 3 of the agenda), a strategic discussion should take place among the Members. This paper prepared by the Secretariat aims at providing guidance for such discussion with background information and questions to be considered by the Members. The list of questions is not exhaustive. It is expected that the discussion will help Members of the Network and the Secretariat in refining the draft Work Programme and support its implementation in the upcoming two years and for the long term (topic 3 of the agenda).

Summary of document
The discussion document provides some background information on the EU cooperation on HTA and outlines some possible questions the Members of the Network are asked to reflect on, namely: - Scope of the cooperation at EU level on production of HTA joint work - Impact of the EU HTA cooperation on national decision making process.

Format of procedure
After a short introduction by the Secretariat, the Chair will open the discussion on the suggested questions. Member may want to raise also other questions. After the discussion, the chair will ask the Members whether a sub-group of the Network should be set up to prepare a vision paper. The draft Multi-annual work plan foresees a discussion on the draft document during the first meeting in 2014, and its endorsement during the second meeting.

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1. FACTS

Health Technology Assessment has proved to be an efficient tool to provide the basis for notably evidence-based decisions for pricing and reimbursement of health technologies[1] in Member States and consequently contribute to improve patients' access to effective interventions including medicines and device.

A recent study[2] supported by the EC on the cost benefits of joint activities on HTA at EU level, indicates that increased and sustainable cooperation at EU level in HTA is associated with significant scientific and economic return for HTA Agencies and Industry. The study estimated that increased production of "joint HTAs" leads to efficiency gains as production costs per Report in the Member States will be lowered. Such gains can amount up to 19 million € per annum, shared between HTA Agencies and industry.

Sustainable cooperation at EU level on HTA is also expected to lead to more efficient use of resources at national level and enable specialised expertise available throughout Europe without the need to have such expertise "physically" present in all 28 Member States.

The European Commission has been supporting cooperation at scientific level between national authorities responsible for HTA for more than 10 years. Member States have themselves dedicated substantial resources to this cooperation. In the forthcoming Health Programme (2014-2020) and Horizon 2020 research programme the Commission is proposing to devote substantial additional funding to continue to facilitate such cooperation, using the financial instruments foreseen (tenders, grants). Within the appropriate institutional framework, namely the relevant Programme Committees, Member States will have to vote on the proposed work programmes and on their co-financing part.

In the long run, it will be necessary to identify and implement a self-sustainable model, not relying largely on EU funding, notably because the Financial Regulation of the EU bans recurrent financing through projects for permanent tasks.

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[1] Health technologies include medicines, medical devices and complex interventions i.e. combining medicines, procedures and/or medical devices.

[2] European Cooperation on Health Technology Assessment – economic and governance analysis of the establishment of a permanent secretariat – http://ec.europa.eu/health/technology_assessment/docs/study_ecorys_european_cooperation_hta_en.pdf

2. THE SUGGESTED QUESTIONS

The Members are invited to comment on the following elements.

2.1. Scope of the work

2.1.1. Technologies and systems

Pharmaceutical products represent an average of 15 to 20% of the overall health care budgets, and around 80% of all HTA's are made on pharmaceutical products, notably as part of the decision making process on pricing and reimbursement of individual drugs. HTA methodologies for pharmaceutical products are therefore well elaborated and EUnetHTA is well embarked in the production of HTA evidence generation reports.

For medical devices the situation is different: the efficacy of a new device depends not only on the device itself, but also on how it is used. This means that the training of health personnel, the hospital process etc. makes clinical studies of devices more challenging and comparisons of technologies more complex. EUnetHTA is also addressing this area, even if HTA methodologies for assessing devices are so far less standardized than for pharmaceutical products.

More and more assessments are needed on complex interventions i.e. a combination of pharmaceuticals, a device and/or a specific intervention (for example a surgical procedures or a screening programme). Substantial efforts are being conducted through 4 FP7 research (DG RTD) and ICT projects (DG CONNECT), the Innovative Medicine Initiative (IMI) to further enhance and strengthen specific methodological challenges.

On an even broader perspective, the reflection process under the Working Party on Public Health at Senior Level,[3] aiming at identifying effective ways of investing in health is examining mainly macro-economic issues, including planning and prioritisation of investments. However, some of the working groups[4] set up are expected to touch upon micro level/ single technologies (i.e. relative effectiveness of pharmaceutical products) and intermediate level issues (i.e. comparing the effectiveness of mental care practices between countries). HTA issues can be relevant in this exercise.

The Commission also set up an expert panel on effective ways of investing in health [5] aiming at providing scientific advice and knowledge on the sustainability of healthcare systems. The panel could be mandated for delivering opinions which have HTA dimensions.

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[3] Council conclusions: "Towards modern, responsive and sustainable health systems" 3095th EMPLOYMENT, SOCIAL POLICY, HEALTH and CONSUMER AFFAIRS Council meeting, Luxembourg, 6 June 2011

[4] The Working Party has set up 5 working groups to look at the following topics: 1.health and the European Semester Agenda; 2.Key success factors for investing in health through cohesion policy (where HTA is considered as a relevant tool to prioritise investment; and where structural funds may also be devoted to reinforce national HTA capacities); 3 Rational use of pharmaceuticals; 4.Integrated care and hospital management; 5.Performance assessment of health systems.

[5] Commission decision 2012/198/6

Last but not least, the European Semester agenda[6] and several of the Country Specific Recommendations on healthcare refer to cost effectiveness and more efficient use of resources. These Recommendations are based on the national reforms programmes, presented by Member States and assessed by the Commission. Member States may thus integrate HTA related elements in their national reform programmes, from a macro/intermediate perspective.

Should EU action on HTA for the next 5 years or for the long term continue focusing on pharmaceutical products and medical devices or consider evaluating more complex interventions?

Should EU action on HTA also address issues related to the performance of health systems, including tools for planning and prioritising investments, and whether interaction should be foreseen between the HTA Network and the initiatives mentioned above?

2.1.2. HTA domains

The Joint Action EUnetHTA has developed an HTA core model and identified different domains to be addressed when performing HTAs. The HTA core model contains 9 domains. Thus the methodology can be applied in a holistic way to assess organisational and economic consequences of healthcare processes and systems, including cost effectiveness.

The scope of the pilots on-going in EUnetHTA are focusing on domains which are necessary to assess clinical effectiveness of the selected technologies; though initiatives are currently being launched to consider also the economic dimension[7].

The Network of national and regional competent authorities, on pricing and reimbursement policies of pharmaceutical products, supported by the Commission (DG Enterprises and Industries) aims notably at exchanging information and follows the work of EUnetHTA.

Should the Network in its strategic recommendations focus on the clinical dimension of HTA only or consider other dimensions such as the organisational and economic ones?

[6] The EU Semester Agenda is a yearly cycle of economic policy coordination lead by the EU Institutions to support Member States in their efforts to meet Europe 2020 targets and implement growth-enhancing policies. As part of this process each year the European Commission undertakes a detailed analysis of EU Member States' programmes of economic and structural reforms and provides them with recommendations for the next 12-18 months. Member states have to respond with National Reform Programmes. Healthcare is part of the European Semester.

[7] EUnetHTA WP 7, Guidelines on Cost effectiveness of technologies.

2.2. Benefits of the EU HTA cooperation for national decision making processes

Substantial efforts have been made by Member States and the EU to enable HTA bodies to agree on common methodologies and guidelines.

Now the focus of EUnetHTA is to increase its "production" of joint work and start piloting activities. To achieve more efficient use of HTA capacities, from Member States, from the EU and from stakeholders, and to avoid duplication of assessments, as aimed at by the cross-border health care Directive, it is important that EU joint work on HTA is taken up by national agencies, adapted and re-used locally for the production of national or regional HTA reports.

This should of course be done within the limits of the EU competences, not interfering in the final decisions made at national or regional levels on the uptake, investments and disinvestments in health technologies.

Can a EU HTA business model be developed to enable broader joint production at EU level and can the Network facilitate the reuse of the tools and of the evidence generation produced at EU level into the national decision making processes?

2.3. HTA and the regulatory processes

Currently the different phases enabling patients to access new technologies, from research to regulatory approval and CE marking are not optimally interacting.

This often results in different requirements from different regulatory authorities (EU or national) and HTA bodies, and may delay access to technologies. While specificity must be maintained to meet the objectives of each phase, more synergy and de-fragmentation should be achieved. This would speed patient access to innovative technologies, contribute to increase business predictability and the reduction of administrative hurdles, for public regulators, technology developers, while safeguarding the criteria applied for placing technologies on the EU market.

The same apply to requirements which come up after the recommendations made by the HTA bodies, i.e. by the payers, namely the incentive to collect data on relative effectiveness in post marketing phase.

How far should the upcoming HTA cooperation explore avenues for interaction and synergies of the successive phases of technology development, licensing and market access?